IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MINNESOTA

CYNTHIA GRIFFIN, *Plaintiff* v. COLOPLAST CORP., *Defendant*.	**COMPLAINT FOR DAMAGES AND JURY DEMAND** Case Number: 0:22-cv-2110

Plaintiff CYNTHIA GRIFFIN ("Plaintiff") files this Complaint, and for causes of action against Defendant COLOPLAST CORPORATION ("Coloplast" or "Defendant"), alleges as follows:

PARTIES

1. Plaintiff CYNTHIA GRIFFIN is a citizen and resident of Scottsdale, Arizona who was implanted with Defendant's defective Altis medical device in Scottsdale, Arizona.

2. Defendant COLOPLAST CORPORATION is a corporation organized and existing under the laws of the State of Delaware, maintaining its principal place of business at 1601 West River Road North, Minneapolis, Minnesota 55411.

JURISDICTION AND VENUE

3. The Court has subject matter jurisdiction pursuant to Minn. Stat. §§ 8.31 and 484.01. Personal jurisdiction over Defendant is proper because it purposefully availed themselves of the privilege of conducting activities within the State of Minnesota and, in fact, maintain regular and continuous business contacts within the State. Coloplast

maintains its North American headquarters in Minneapolis, Minnesota.

4. Venue is proper in this Court pursuant to Minn. Stat. § 542.09, because: (1) Defendant did business in this county by manufacturing, selling, marketing, and/or warranting the Altis device; (2) some of the acts and transactions described herein occurred within this county; and (3) some of the injuries and causes of action alleged herein emanated from or occurred in this county.

FACTUAL BACKGROUND

Treatment of Pelvic Organ Prolapse and Stress Urinary Incontinence

5. At all times material to this action, Defendant was in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, advertising, and delivering, and introducing into interstate commerce, including, *inter alia*, within the United States and within the State of Minnesota, either directly or indirectly through third parties, subsidiaries or related entities, a line of pelvic mesh products (the "Pelvic Mesh Products"), including the Coloplast Altis mid-urethral single incision sling system, the product implanted into Plaintiff (the aforementioned "Altis"). These products were designed primarily for the purpose of treating stress urinary incontinence as well as pelvic organ prolapse.

6. A pelvic organ prolapse ("POP") occurs when a pelvic organ, such as the bladder, drops ("prolapses") from its normal position and pushes against the walls of the vagina. Prolapse can happen if the muscles that hold the pelvic organs in place become weak or stretched from childbirth or surgery. More than one pelvic organ can prolapse at

the same time. Organs that can be involved in a pelvic organ prolapse include the bladder, the uterus, the bowel and the rectum.

7. Stress urinary incontinence ("SUI") is a type of incontinence characterized by leakage of urine during moments of physical stress, such as coughing, laughing, or sneezing. At all relevant times, the Altis was intended to be used, and for Plaintiff was used, to treat stress urinary incontinence.

8. Each of these Pelvic Mesh Products were cleared (not approved) for sale in the United States after the Defendant made assertions to the Food and Drug Administration of "Substantial Equivalence" under Section 510(k) of the Food, Drug and Cosmetic Act; this process does not require the applicant to prove safety or efficacy.

9. Surgical mesh is a medical device that is generally used to repair weakened or damaged tissue. This is the type of mesh used in Defendant's Pelvic Mesh Products, including the Altis product at issue in this case. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair POP or to support the urethra to treat SUI. Most pelvic mesh products, including the Altis product at issue in this case, are comprised of non-absorbable, synthetic, monofilament polypropylene mesh.

10. Despite claims that polypropylene mesh is inert, the scientific evidence shows that this material as implanted in Plaintiff and others is biologically incompatible with human tissue, and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population

implanted with Defendant's Pelvic Mesh Products. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, and causes chronic inflammation of the pelvic tissue, shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response, and chronic pain. It also can cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the mesh.

11. When the Pelvic Mesh Products, including the Altis product at issue in this case, are inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

12. In 1996, the FDA cleared the first pelvic mesh products for use in the treatment of SUI. These products include products manufactured, marketed, and distributed by Defendant. These products were and are approved by the FDA under the abbreviated 510(k) approval process. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed before May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted with regard to these pelvic mesh products, including the Altis product at issue in this case.

History of the Altis Product

13. Many of the Defendant's Pelvic Mesh Products, including the Altis product at issue in this case, were developed and/or acquired as a result of the acquisition by Coloplast of Mentor Corporation ("Mentor")'s surgical, urological, clinical, and consumer

healthcare business segments in June 2006.

14. On February 8, 2001, Mentor announced the purchase of Porges S.A., a subsidiary of Sanofi-Synthelabo. At the time, Porges held the leading market share for urological products in France and held a strong position throughout Europe was one of the largest manufacturers of urological products, supplying a complete range of products including pelvic mesh products.

15. On January 24, 2005, Mentor applied for 510(k) clearance for a new product, the Aris(TM) Trans-Obturator Tape and Surgical Kit. In the 510(k) Summary (K050148) for the Aris, Defendant states "the Mentor Aris Trans-obturator Tape and the Kit are substantially equivalent in material, function, performance and design to the Mentor ObTape Trans-Obturator Tape and Surgical Kit cleared under 510(k) K031767 and K042851, respectively. It is also substantially equivalent to other urethral support tape products currently on the market." The Aris received 510(k) clearance from the FDA on March 9, 2005.

16. In May 2005, Mentor announced the U.S. launch of its new Aris(TM) Trans-Obturator Tape. According to Mentor's launch reports, "specifically designed to utilize Mentor's patented Trans-Obturator Technique (T.O.T.(TM)), Aris represents the newest technical achievement and advanced generation of trans-obturator slings for the treatment of stress urinary incontinence in women." "The introduction of Aris furthers Mentor's position as a pioneer of the trans-obturator method for treating stress incontinence in women," commented Joshua H. Levine, President and Chief Executive Officer of Mentor Corporation. "We are committed to driving innovation in the field of women's health to

provide better solutions for physicians and the patients they serve." Analytic Biosurgical Solutions ("ABISS") FDA registration lists its proprietary device as "Mentor Altis Trans-Obturator Tape and Surgical Kit."

17. On October 12, 2005, ABISS and Mentor entered into a number of agreements pursuant to which ABISS licensed a number of ABISS' products to Mentor, which were thereafter marketed by Mentor under its trademarks, including its Aris trademark. On June 2, 2006, Mentor sold its surgical, urological, clinical and consumer healthcare business segments to Coloplast for $461,145,398, including *inter alia*, Mentor's October 12, 2005, agreements with ABISS and Mentor's Aris and Novasilk Pelvic Mesh Products.

18. At all times, the product marketed and sold in the United States as "Mentor Aris Trans-Obturator Tape and Surgical Kit" was manufactured by ABISS and, at all times after October 2, 2006, the product "Mentor Aris Trans-Obturator Tape and Surgical Kit" was exclusively marketed and sold in the United States by Coloplast Corp. from its principal place of business in Minneapolis, Minnesota. ABISS is registered with the FDA, Registration Number 3004756681, as the manufacturer of "Mentor Aris Trans-Obturator Tape and Surgical Kit."

19. On December 5, 2005, Mentor obtained 510(k) clearance for Mentor NovaSilk Mesh. Mentor NovaSilk Mesh is a permanent, synthetic knitted propylene mesh that is square in shape and is a sterile, single use device. The Mentor NovaSilk Mesh obtained 510(k) clearance based on substantial equivalence in material, function, performance, and design to the Gynemesh Prolene Soft (Polypropylene) Mesh cleared

under 510(k) K013718 and knitted polypropylene already in use under Mentor's Altis Sling cleared under 510(k) K050148. Joshua H. Levine, President and Chief Executive Officer of Mentor Corporation commented, "The addition of NovaSilk to Mentor's expanding portfolio of women's health products for pelvic organ prolapse or stress urinary incontinence reinforces the commitment of our urology franchise to surgeons and the patients they serve by providing high quality product offerings and customer service and support."

20. Coloplast Corp.'s annual report for 2009-2010 reported that "the majority of our acquired patents and trademarks are associated with the acquisition of Mentor's urology, business in 2006." The annual report also said that Mentor signed "a non-competition clause prohibiting Mentor (the seller) from selling urology products for the next seven years…."

21. Coloplast Corp. began marketing the Exair Prolapse Repair System in May 2009 to treat pelvic organ prolapse. This product is made of NovaSilk Mesh, precut into the necessary shape with four mesh arms extending from the main body, which are used to implant the device. This product obtained 510(k) clearance based on its substantial equivalence with Coloplast Corp.'s (formerly Mentor's) NovaSilk Mesh, and Gynecare Prolift Total Pelvic Floor Repair System cleared under pre-market notification number K071512 on May 15, 2008.

22. On October 29, 2010, Coloplast Corp. acquired Mpathy Medical Devices, Inc. ("Mpathy"). Mpathy was founded in 2003, with the aim of developing less invasive surgical solutions for the treatment of female stress urinary incontinence and pelvic organ

prolapse. Mpathy's core product lines included Minitape® and Omnisure® for stress urinary incontinence, and the Restorelle® family for pelvic organ prolapse. Defendant Coloplast Corp. said of the acquisition that Coloplast Corp.'s market position in Surgical Urology and Female Pelvic Health would immediately strengthen based on Mpathy's product portfolio including slings, mini-slings and meshes for stress urinary incontinence and pelvic floor repair and material portfolio including Smartmesh® technology.

23. On November 5, 2012, Coloplast A/S received clearance for the Altis Single Incision Sling System (K121562) as a device substantially equivalent in performance, indications, design, and materials to Coloplast's Aris System (previously Mentor's), American Medical System's MiniArc System, and C.R. Bard Adjust Adjustable Single Sling Incision.

24. Coloplast Corp.'s website describes its various products, including those for treating (i) "Pelvic Organ Prolapse" and (ii) "Stress Urinary Incontinence," including "Sling Procedures." A press release issued by Coloplast Corp. described Coloplast Corp.'s new corporate headquarters at 1601 West River Road in Minneapolis and stated that "Denmark-based Coloplast…selected north Minneapolis as the new home for its North American headquarters in 2006." According to the press release the new headquarters "will include one of the company's three global Innovation Centers."

Warnings Regarding Pelvic Mesh Products

25. On July 13, 2011, the FDA issued a new warning regarding serious complications associated with pelvic mesh products, such as the Pelvic Mesh Products manufactured, marketed, and distributed by Defendant. In this warning, the FDA indicated

that "serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**." (emphasis in the original). The FDA had also received increased reports of complications associated with the pelvic mesh products used in both pelvic organ prolapse and stress urinary incontinence cases.

26. The FDA Safety Communication also stated, *"Mesh contraction* (shrinkage) is a *previously unidentified risk of* transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA . . . Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." (emphasis in original).

27. The FDA Safety Communication further indicated that the benefits of using pelvic mesh products instead of other feasible alternatives did not outweigh the associated risks. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risks."

28. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the "White Paper"). In the White Paper, the FDA noted that published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

29. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that

using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risks." (Emphasis in original).

30. The White Paper further stated that "these products are associated with serious adverse events . . . Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair." In its White Paper, the FDA advises doctors to, *inter alia*, "[r]ecognize that in most cases POP can be treated successfully without mesh thus avoiding the risk of mesh related complications." The White Paper concludes by stating that the FDA "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

31. On August 25, 2011, Public Citizen, a consumer advocacy group, submitted a petition to the FDA seeking to ban the use of pelvic mesh products in pelvic repair procedures. In its Petition, Public Citizen warned that pelvic mesh products should be recalled because they offer no significant benefits but expose patients to serious risks and the potential for permanent life-altering harm. Joining Public Citizen as co-petitioners were Dr. L. Lewis Wall, a professor of obstetrics and gynecology at Washington University in St. Louis, and Dr. Daniel S. Elliott, a urologic surgeon specializing in female urology at the Mayo Clinic in Rochester, Minnesota.

32. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists ("ACOG") and the American Urogynecologic Society ("AUGS") also identified physical and mechanical changes to the transvaginal mesh inside

the body as a serious complication associated with transvaginal mesh, stating:

> **There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh… Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.**

33. The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk."

34. As is known to Defendant, the risks associated with POP repair are the same as SUI repair. However, the data regarding the magnitude and frequency of these known risks are not as developed as the data on POP repair. The FDA recognized this, as demonstrated by its Section 522 Orders issued to manufacturers of pelvic mesh products used to treat SUI in January of 2012.

35. In September 2011, the FDA acknowledged the need for additional data and noted in "Surgical Mesh For Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence" that the literature and information developing on SUI repair with Pelvic Mesh Products "indicates that serious complications can occur . . . [and] a case can be made for additional premarket and/or post market studies to better address the risk/benefit of all mesh products used for SUI."

36. After the 2011 FDA notification that mesh complications from POP repairs were "not rare," a 2013 article was published that stated: "as outlined in the FDA notifications, patients should be forewarned that some transvaginal mesh complications are life altering and might not always be surgically correctable. Furthermore, that study noted

that "the women who received both MUS and TM represented a complicated surgical group. Fifteen women (43%) required MUS takedown concurrently with prolapse mesh excision. Two-thirds of these women had associated chronic pelvic pain and vaginal pain, in addition to their urinary symptoms."

37. On April 16, 2019, the FDA ordered all manufacturers of surgical mesh intended for transvaginal repair of anterior compartment prolapse (cystocele) to stop selling and distributing its products immediately. In fact, the FDA has determined that the manufacturers, Boston Scientific and Coloplast specifically, have not demonstrated reasonable assurance of safety and effectiveness for these devices, which is the premarket standard that now applies to them since the agency reclassified them into class III (high risk) in 2016.[1]

38. Defendant knew or should have known that its Pelvic Mesh Products, including the Altis product at issue in this case, unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks. At the time Defendant began marketing the Altis, Defendant was aware that the Altis was associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011, safety communication.

Resulting Injury from Defendant's Pelvic Mesh Products

39. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with Defendant's Pelvic Mesh Products

[1] www.fda.gov/medical-devices/implants-and-prosthetics/urogynecologic-surgical-mesh-implants.

include, but are not limited to: erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, obturator nerve damage/irritation, pudendal nerve damage/irritation, pelvic floor damage, chronic pelvic pain, chronic extrapelvic pain, chronic groin pain, chronic thigh pain, emotional distress and mental anguish, and other debilitating complications. In addition, affected women, including Plaintiff, will need to be continuously monitored because of being implanted with Defendant's Pelvic Mesh Products.

40. In many of these cases, including that of the Plaintiff, women have had or will have to undergo extensive medical treatment, including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia. Removal of contracted, eroded and/or infected transvaginal mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

Facts Specific as to Plaintiff

41. On September 1, 2017, at Honor Healthcare Shea Medical Center in Scottsdale, Arizona, Dr. Ahmed Akl implanted Plaintiff CYNTHIA GRIFFIN with a Coloplast Altis Single Incision Sling, as follows:

SYSTEM SLING GYNE SZ1 7.75CM MONO ALTIS - LOG268695

Inventory Item: SLING SYSTEM GYNE SIZE-1 7.75CM MONO ALTIS	Serial no.:	Model/Cat no.: 519650
Implant name: SYSTEM SLING GYNE SZ1 7.75CM MONO ALTIS - LOG268695	Laterality: N/A	Area: Urethra
Manufacturer: COLOPLAST	Date of Manufacture:	
Action: Implanted	Number Used: 1	
Device Identifier:	Device Identifier Type:	

42. The Altis is a medical device designed, manufactured, and marketed by Defendant for the treatment of stress urinary incontinence. The Altis implanted in Plaintiff was in the same or substantially similar condition as it was when it left Defendant's possession, and in the condition directed by and expected by Defendant. Plaintiff's treating physicians implanted the Altis properly and appropriately.

43. Although the system was intended to treat SUI, neither Plaintiff nor her healthcare providers were warned that the Altis was defective and negligently designed and marketed, as discussed further herein.

44. Following implantation of the Altis, Plaintiff began experiencing dyspareunia, pelvic pain, vaginal pain, and recurring urinary incontinence, among other symptoms. She was subsequently diagnosed with pudendal neuralgia and underwent removal surgery as well as pudendal nerve blocks, and is receiving ongoing medical treatment for her injuries, her future prognosis unknown.

DISCOVERY RULE

45. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and to the extent necessary would allege as follows:

46. Plaintiff could not have reasonably discovered the occasion, manner and/or means by which Defendant's breach of duty occurred until within the applicable limitations period for the filing of this complaint. Further, Plaintiff did not and, exercising reasonable diligence, including consultation with medical professionals, could not discover the existence of her legal cause of action or the injuries caused by Defendant's breach of duty and/or defective products until within the applicable limitations period for the filing of this complaint. Defendant continues to deny that its products are defective or cause injuries such as those suffered by Plaintiff and Defendant continues to manufacture, market, and sell all or some of the products at issue. Any applicable statute of limitations has been tolled by the knowing and active concealment and denial of material facts known by Defendant when Defendant had a duty to disclose and/or by the application of the discovery rule.

COUNT I: STRICT LIABILITY – DESIGN DEFECT

47. At all relevant times, Defendant designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold and distributed the Altis product that was implanted into Plaintiff.

48. Defendant's Altis product was expected to, and did, reach the intended consumers, handlers, and persons coming into contact with Defendant's pelvic mesh products without substantial change in the condition in which it was produced, manufactured, sold, distributed, labeled, and marketed by Defendant.

49. At all relevant times, Defendant's Altis product was manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition, which was dangerous for use by the public, and in particular, by Plaintiff.

50. Defendant's Altis product was defective in design and formulation in that, when it left Defendant's hands, the foreseeable risks exceeded the benefits allegedly associated with the design of the Altis product.

51. Defendant's Altis product was defective in design because, when it left Defendant's hands, it was unreasonably dangerous and was also more dangerous than the ordinary consumer would expect.

52. At all relevant times, Defendant's Altis product was in a defective condition, and was and is inherently dangerous and unsafe when used in the manner instructed and provided by Defendant.

53. At the time that the Altis product was implanted into Plaintiff, it was being used for its intended use in a manner normally intended—namely, to treat stress urinary incontinence. Defendant had a duty to create a product, to wit, its Altis device, that was not unreasonably dangerous for its normal, common, intended use.

54. Plaintiff, her physicians, and her other healthcare providers could not, by the exercise of reasonable care, have discovered the defects in this product or perceived their danger.

55. Defendant knew or should have known that its Pelvic Mesh Products, including the Altis product at issue in this case, unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks. At the time Defendant began marketing the Altis, Defendant was aware that the Altis was associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011, safety communication.

56. The Altis was designed to be permanently implanted into a woman's body yet the product changes after implantation; it contracts over time which inter alia, can pull or compress nerves, muscles, and other soft tissues important for sexual function, mobility, bowel function, and bladder function. These product changes occur while the product is implanted.

57. Moreover, despite claims that polypropylene mesh is inert, the scientific evidence shows that this material as implanted in Plaintiff is biologically incompatible with human tissue and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendant's Pelvic Mesh Products, including the Altis product at issue herein. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, causes chronic inflammation of the pelvic tissue, causes shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response and chronic pain, cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the polypropylene mesh.

58. To this day, the Altis continues to be marketed to the medical community and to patients as a safe, effective, and reliable medical device, implanted by safe, effective, and minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of POP and SUI, and other competing products.

59. Defendant omitted and downplayed the risks, dangers, defects, and disadvantages of its Pelvic Mesh Products, including the Altis product at issue, and advertised, promoted, marketed, sold and distributed the its Pelvic Mesh Products, including the Altis product at issue, as safe medical devices when Defendant knew or should have known that the Pelvic Mesh Products were not safe for their intended purposes, and that the products would cause, and did cause, serious medical problems, and in many patients, including Plaintiff, catastrophic injuries. Further, while some of the problems associated with the pelvic mesh products, including the Altis, were made known to physicians, the magnitude and frequency of these problems were not disclosed and were hidden from physicians.

60. Contrary to Defendant's representations and marketing to the medical community and to the patients themselves, its Pelvic Mesh Products, including the Altis product at issue, have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff, making them defective under the law.

61. Defendant failed to design and establish a safe, effective procedure for removal of its Pelvic Mesh Products, including the Altis product at issue, or to determine if a safe, effective procedure for removal of the Pelvic Mesh Products exists.

62. Feasible, suitable, and safer alternative designs to Defendant's Pelvic Mesh Products, including the Altis product at issue, have existed at all times relevant and in reasonable probability would have prevented or significantly reduced the risk of Plaintiff's

injuries without substantially impairing the product's utility. Said safer alternative designs were economically and technologically feasible at the time the Altis product left the control of Defendant by the application of existing or reasonably achievable scientific knowledge. Said safer alternatives designs include, but are not limited to: (1) traditional abdominal surgery using sutures to attach the urethra to a ligament in the pelvis (known as the "Burch procedure"); (2) autologous fascia sling; (3) an allograft sling such as Repliform; (4) a retropubic sling; (5) a retropubic mini-sling, such as the TFS device made by TFS Surgical; (5) a sling with less polypropylene, such as Ultrapro; (6) a sling with a lighter-weight, larger pore mesh, such that used in the Ethicon Prolift+M; (7) a sling with a polymer-based polypropylene alternative, such as PVDF; and (8) a retropubic mini-sling comprised of the materials listed in (5)-(7).

63. The specific nature of defects for Defendant's Altis device at issue in this case includes, but is not limited to, the following:

(a) The use of polypropylene in the Altis and the adverse tissue reactions and host defense response that result from such material, causing adverse reactions and serious, permanent injuries including, but not limited to, painful recurrent erosions and associated intractable pain;

(b) The design of the Altis to be inserted into and through an area of the body that is blood vessel rich, nerve dense, and bacteria laden leading to excessive blood loss and vascular damage, permanent nerve injury and associated chronic, intractable neuropathic pain, contaminated permanently-implanted mesh causing chronic infections, subclinical infections and biofilms, enhanced chronic

inflammatory response, chronic wound healing with tissue destruction, as well as numerous other adverse reactions and serious and permanent injuries;

(c) The use and design of introducers and anchors in the Altis sling, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

(d) The procedure to place the Altis sling requires blindly placing the anchors of the device through the thigh and obturator fossa that can injure major nerves that contribute to sexual function, contribute to mobility, and contribute to bowel and bladder function;

(e) Biomechanical issues with the design of the Altis which results in a non-anatomic condition leading to contraction or shrinkage of the mesh inside the body, that in turn causes surrounding tissue to become eroded, inflamed, fibrotic and infected, resulting in serious and permanent injury;

(f) The propensity of the mesh design characteristics of the Altis for plastic deformation when subjected to tension both during implantation and once implanted inside the body which causes the mesh, or portions thereof, to be encapsulated in a rigid scar plate which leads to nerve entrapment, bacterial entrapment, tissue destruction, enhanced inflammatory and fibrotic response and chronic pain;

(g) The propensity of the mesh used in the Altis to become rigid and inflexible, causing it to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where the product is implanted, and causing discomfort and pain with

normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

(h) The propensity of the mesh used in the Altis for degradation or fragmentation over time, which causes an increased surface area that leads to enhanced chronic inflammatory and fibrotic reaction, causes a "barbed wire" or "saw blade" effect by the fragmented surface "sawing" through the tissue, leads to bacteria harboring in the fragmented, peeled and split fiber surface which in turn leads to chronic infections at the mesh surface, and results in continuing injury over time; and

(i) The inability of surgeons to effectively treat many of these conditions due to the integration of the mesh into the pelvic tissue and thus the inability to safely remove or excise the mesh once a complication occurs.

64. Defendant designed, developed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product—the Altis product at issue in this case—that created an unreasonable risk to the health of consumers and to Plaintiff in particular and Defendant is therefore strictly liable for the injuries and damages sustained by Plaintiff.

65. The defects in Defendant's Altis product were substantial and contributing factors in causing Plaintiff's injuries.

66. As a direct, foreseeable, and proximate result of Defendant's aforesaid acts and omissions, and as the direct, foreseeable, and proximate result of the implantation of Defendant's Altis product into Plaintiff, Plaintiff was caused to suffer, did suffer, and will

continue to suffer from physical, emotional, economic and other injury. In addition and in the alternative, Plaintiff suffered from pre-existing injuries/conditions which were aggravated, exacerbated, and/or accelerated by implantation of the Altis device.

COUNT II: STRICT LIABILITY – MARKETING DEFECT (FAILURE TO WARN)

67. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further allege as follows:

68. The Altis product was manufactured, designed, marketed, labeled and sold in a defective condition, for use by the Plaintiff's physicians and/or healthcare providers and all other consumers of the product, making the product unreasonably dangerous.

69. Defendant's Pelvic Mesh Products, including the Altis product at issue, as designed, manufactured, distributed, sold and/or supplied by Defendant, were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendant's knowledge of lack of safety.

70. Defendant underreported and continues to underreport information about the propensity of its Pelvic Mesh Products, including the Altis product at issue, to fail and to cause injury and complications and have made unfounded representations regarding the efficacy and safety of its Pelvic Mesh Products, including the Altis product at issue, through various means and media.

71. Defendant failed to perform proper and adequate testing and research in order to determine and evaluate the nature, magnitude and frequency of the risks attendant to its Pelvic Mesh Products, including the Altis product at issue.

72. The Altis product at issue was at all times utilized and implanted in a manner intended and/or foreseeable to Defendant, as Defendant generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physician.

73. Defendant knowingly provided incomplete and insufficient training and information to physicians regarding the use of its Pelvic Mesh Products, including the Altis product at issue, and the aftercare of patients implanted with those Pelvic Mesh Products.

74. At all relevant times herein, Defendant continued to promote its products as safe and effective even when no clinical trials had been done supporting long-term or short-term efficacy or safety.

75. In doing so, Defendant failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with its Pelvic Mesh Products, including the magnitude and frequency of these risks.

76. At all relevant times herein, Defendant failed to provide sufficient warnings and instructions that would have put Plaintiff, the medical community, Plaintiff's treating physicians, and the general public on notice of the dangers and adverse effects caused by implantation of the Defendant's Pelvic Mesh Products, including the Altis product at issue.

77. The risk of serious injuries was known or should have been known to Defendant, but in spite of these risks, Defendant continued to market the Altis for transvaginal use to physicians and patients, including Plaintiff and Plaintiff's healthcare providers, without adequate warnings.

78. In the Altis IFU, as well as the marketing materials Defendant prepared and disseminated to patients and healthcare providers, Defendant omitted critical information

regarding the risks and potential complications of the Altis product at issue in this case.

79. Specifically, Defendant failed to properly and adequately warn and instruct Plaintiff and her healthcare providers as to the following (subsequently referred to as the "Risks and Potential Complications"):

a. That the Altis was not adequately studied prior to launch for safety and efficacy;

b. That the Altis has propensities to contract, retract, and/or shrink inside the body;

c. That the Altis has propensities for degradation, fragmentation, and/or creep;

d. That the Altis' inelasticity prevents proper mating with the pelvic floor and vaginal region;

e. The magnitude of the risk of mesh erosion or extrusion;

f. The risk of chronic inflammation resulting from the Altis;

g. The risk of chronic infections resulting from the Altis;

h. The risk of developing chronic regional pain syndrome as a result of chronic inflammation/infection;

i. The risk of permanent vaginal or pelvic scarring as a result of the Altis;

j. The risk and/or magnitude of recurrent, intractable pelvic pain, nerve pain, and other pain resulting from the Altis;

k. The risk of secondary nerve irritation to the pudendal nerve;

l. The risk of direct nerve injury to the obturator nerve;

m. The risk of secondary nerve irritation to the obturator nerve;

n. The magnitude of the risk of dyspareunia (painful sexual intercourse) in patients;

o. That the Altis may result in dyspareunia that makes vaginal penetration impossible;

p. The risk of vulvar, perineal, or perianal allodynia;

q. The frequency with which the need for corrective or revision surgery to adjust or remove the Altis may occur in patients;

r. The nature, magnitude, and frequency of the risk of acute and long-term complications that could arise as a result of implantation of the Altis in patients;

s. The hazards associated with the Altis, including obturator and pudendal neuralgia, and, permanent nerve damage, and pelvic floor and groin myalgia;

t. That treatment of SUI with the Altis exposes patients to greater risk than feasible available devices for SUI, including pelvic mesh products utilizing alternative polypropylene material or non-polypropylene surgical products, alternatives, and procedures;

u. That treatment with the Altis makes future surgical repair more difficult than feasible available alternatives;

v. That the Altis offers no improvement in efficacy compared to non-mesh repairs and non-mesh repairs do not place the obturator or pudendal nerve at risk acutely or over time;

w. That use of the Altis puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

x. That removal of the Altis due to complications may significantly impair the patient's quality of life;

y. That complete removal of the Altis may not be possible;

z. That complete removal of the Altis may not result in complete resolution of the complications, including pain;

aa. The foreseeable and unavoidable risk of acute obturator or pudendal neuralgia or obturator and/or pudendal neuralgia occurring months or years after implantation;

bb. The magnitude of the risk of obturator and/or pudendal neuralgia; and

cc. The risk of permanent injury and pain to the muscles and soft tissues of the pelvic floor that may occur acutely after implantation or become symptomatic months or years after implantation.

80. Arguing further, Defendant failed to properly and adequately warn and instruct Plaintiff and her healthcare providers as to the proper candidates for, and the safest and most effective methods of, implantation and use of Defendant's Pelvic Mesh Products, including the Altis Pelvic Mesh Product at issue in this case. Defendant also failed to properly and adequately warn and instruct Plaintiff and her healthcare providers with regard to the inadequate research and testing of the Pelvic Mesh Products, including the Altis Pelvic Mesh Product at issue in this case, and the complete lack of a safe, effective procedure for removal of the Pelvic Mesh Products.

81. The Pelvic Mesh Product at issue herein was expected to, and did, reach the intended consumers, handlers, and persons receiving the products, including Plaintiff, with no substantial change in the condition in which the products were designed, produced, manufactured, sold, distributed, labeled and marketed by Defendant.

82. Defendant, by exercising reasonable diligence, could have made such warnings available to Plaintiff, Plaintiff's healthcare providers, and the medical community.

83. As a direct and proximate result of Defendant's failure to provide Plaintiff, Plaintiff's healthcare providers, and the medical community with sufficient or adequate warnings, Plaintiff and Plaintiff's healthcare providers were not adequately informed of the potential dangers and/or defects of the Pelvic Mesh Product at issue herein.

84. Defendant's failure to adequately warn about the risks and dangers associated with the Altis was a proximate cause of the damages and injuries to Plaintiff. Thus, Defendant is strictly liable to Plaintiff.

85. As a direct, foreseeable, and proximate result of Defendant's aforesaid acts and omissions, and as the direct, foreseeable, and proximate result of the implantation of Defendant's Altis product into Plaintiff, Plaintiff was caused to suffer, did suffer, and will continue to suffer from physical, emotional, economic and other injury. In addition and in the alternative, Plaintiff suffered from pre-existing injuries/conditions which were aggravated, exacerbated, and/or accelerated by implantation of the Altis device.

COUNT III-A: NEGLIGENCE (DESIGN DEFECT)

86. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further allege as follows:

87. At all times herein mentioned, Defendant was engaged in the business of designing, manufacturing, labeling, and distributing, supplying, and/or selling its Pelvic Mesh Products, including the Altis device implanted into Plaintiff.

88. Defendant owed to Plaintiff and the public a duty to act reasonably and to exercise ordinary care in designing the Altis device. For the reasons set forth above, Defendant have breached said duty of care in that Defendant failed to use the amount of care in the designing the Altis that a reasonably careful product designer would have used in similar circumstances to avoid exposing others to a foreseeable risk of harm. Defendant's violations the duties of ordinary care and skill owed by Defendant to Plaintiff include but are not necessarily limited to:

(1) Designing a product (the Altis) which, at the time conveyed, was not in conformity with the generally recognized state of the art applicable to the safety of the product at the time the product was designed, manufactured, packaged, labeled and/or sold;

(2) Designing the Altis to be inserted into and through an area of the body that is blood vessel rich, nerve dense, and bacteria laden leading to excessive blood loss and vascular damage, permanent nerve injury and associated chronic, intractable neuropathic pain, contaminated permanently-implanted mesh causing chronic infections, subclinical infections and biofilms, enhanced

chronic inflammatory response, chronic wound healing with tissue destruction, as well as numerous other adverse reactions and serious and permanent injuries without producing any additional therapeutic benefit when compared to other surgical treatment options for SUI;

(3) Designing the Altis to be inserted into and through the obturator internus muscles in the groin, when doing so produces a foreseeable risk of acute and chronic myofascial pain;

(4) Designing the Altis with anchors that are designed to be permanently placed into the obturator internus muscles in the groin;

(5) Designing the Altis to be inserted into and through the obturator internus muscles in the groin, when doing so produces a foreseeable risk of obturator neuralgia and pudendal neuralgia (by aggravating the pudendal nerve as it runs through Alcock's canal) and when other available alternatives, including retropubic slings manufactured by Defendant at the time it was designing the Altis, did not pose this risk;

(6) Designing and using arms and anchors in the Altis which, when placed in the women such as Plaintiff, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

(7) Designing the Altis to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh, causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries without producing any additional therapeutic benefit when compared to other surgical

treatment options for SUI;

(8) Designing a product which creates of a non-anatomic condition in the pelvis, leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturers' instructions that are unique to polypropylene without providing any additional therapeutic benefit when compared to other non-polypropylene surgical treatment options for SUI;

(9) Designing the Altis in such a way that complete removal of the device may be impossible or impossible without multiple surgeries and/or substantial injury to the patient, despite knowledge that in some patients, complete removal might be medically necessary to address their symptoms;

(10) Using polypropylene mesh in the design of the Altis when it was known that the use of polypropylene in the Altis and the foreseeable adverse tissue reactions, host defense response, and immune reactions that result from such material would lead to ongoing degradation of the mesh, shrinkage, perpetual scarification as the mesh degrades all of which have potential to produce adverse reactions and permanent injuries including but not limited to painful recurrent erosions, direct muscle and soft tissue injury, nerve entrapment or irritation of adjacent nerves, and associated intractable neuropathic pain and myofascial pain;

(11) Using polypropylene mesh in the design of the Altis when it was known that the mesh had a propensity to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in

serious and permanent injury to the soft tissues and muscles of the pelvic floor without producing any additional therapeutic benefit when compared to other surgical treatment options for SUI;

(12) Using polypropylene mesh in the design of the Altis when it was known that the mesh had a propensity to "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

(13) Using polypropylene mesh in the design of the Altis when it was known that the inelasticity of the mesh caused the products to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g. intercourse, defecation, or walking) without providing any additional therapeutic benefit when compared to other surgical treatment options for SUI;

(14) Using a polypropylene mesh weight and pore size in the Altis that prevented safe and healthy incorporation of native tissues into mesh fabric, which could lead to fibrotic bridging and encapsulation of the tissues;

(15) Using polypropylene mesh in the design of the Altis when it was known that the mesh had a propensity to degrade, disintegrate, and fragment over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

(16) Using polypropylene mesh in the design of the Altis when it was known that the mesh could produce hyper-inflammatory responses to collagen leading to

problems including chronic pain and fibrotic reaction; and

(17) Using polypropylene mesh in the design of the Altis when it was known that the mesh could stiffen and harden inside the body, producing pain and damage to surrounding tissues and organs.

89. At all relevant times, safer alternative designs to the Altis existed and in reasonable probability would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the product's utility. Said safer alternative designs were economically and technologically feasible at the time the Altis product left the control of Defendant by the application of existing or reasonably achievable scientific knowledge. Such safer alternatives designs include, but are not limited to: (1) traditional abdominal surgery using sutures to attach the urethra to a ligament in the pelvis (known as the "Burch procedure"); (2) autologous fascia sling; (3) an allograft sling such as Repliform; (4) a retropubic sling; (5) a retropubic mini-sling, such as the TFS device made by TFS Surgical; (5) a sling with less polypropylene, such as Ultrapro; (6) a sling with a lighter-weight, larger pore mesh, such that used in the Ethicon Prolift+M; (7) a sling with a polymer-based polypropylene alternative, such as PVDF; and (8) a retropubic mini-sling comprised of the materials listed in (5)-(7).

90. Plaintiff and/or her implanting physician used and was implanted with Defendant's Altis in a manner that was reasonably foreseeable. Plaintiff believed the Altis would address her stress urinary incontinence, and did not know—nor did she have any reason to know, based upon the information provided to her and provided to her implanting physician regarding the risks of the Altis, that she would sustain the injuries from the Altis

described herein.

91. As a direct and proximate result of these design flaws and Defendant's failure to use the amount of care in the designing the Altis that a reasonably careful product designer would have used in similar circumstances to avoid exposing others to a foreseeable risk of harm, Plaintiff has suffered and in all reasonable probability will continue to suffer from dyspareunia, pelvic pain, vaginal pain, pudendal neuralgia, and recurring urinary tract infections, depression, and anxiety, as well as other symptoms and damages, including severe and permanent pain, suffering, disability, impairment of mobility, impairment of sexual function, impairment of bowel and bladder function, future surgical removal of the mesh, loss of enjoyment of life, and economic damages. Plaintiff did not suffer from said injuries prior to implantation of the Altis device, and upon information and belief would not have suffered these injuries absent implantation of the Altis device. In addition and in the alternative, Plaintiff suffered from pre-existing injuries/conditions which were aggravated, exacerbated, and/or accelerated by implantation of the Altis device.

COUNT III-B: NEGLIGENCE (MARKETING DEFECT)

92. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further allege as follows:

93. At all times herein mentioned, Defendant was engaged in the business of marketing, supplying, and/or selling, the Altis, including the Altis implanted into Plaintiff.

94. At all times relevant hereto, Defendant owed to Plaintiff and the public a duty

to act reasonably and to exercise ordinary care with respect to the marketing of the Altis, and to adequately warn of the risk and dangers of the Altis.

95. Defendant owed to Plaintiff, and Plaintiff's physicians, and the public a duty if and when warning about its products, including the Altis, to provide accurate, reliable, and completely truthful information regarding the safety and any dangerous propensities of the Altis and to provide accurate, reliable, and completely truthful information that the Altis was unreasonably dangerous, taking into account the risks and benefits of the product.

96. At all times relevant hereto, Defendant breached the aforementioned duties in that Defendant negligently and carelessly failed to adequately warn regarding the risks of the Altis. Said negligent acts and omissions include but are not limited to:

a. Failing to properly and adequately warn and instruct Plaintiff and her healthcare providers of the design defects, risks and potential complications associated with Defendant's Pelvic Mesh Products, including the Altis Pelvic Mesh Product at issue in this case (said design defects, risks and potential complications being more fully articulated above);

b. Failing to properly and adequately warn and instruct Plaintiff and her healthcare providers as to the proper candidates for the implantation and use of Defendant's Pelvic Mesh Products, including the Altis Pelvic Mesh Product at issue in this case;

c. Failing to properly and adequately warn and instruct Plaintiff and her healthcare providers as to the safest and most effective methods of, implantation and use of Defendant's Pelvic Mesh Products, including the Altis

Pelvic Mesh Product at issue in this case;

d. Failing to properly and adequately warn and instruct Plaintiff and her healthcare providers with regard to the inadequate research and testing of the Pelvic Mesh Products, including the Altis Pelvic Mesh Product at issue in this case;

e. Failing to properly and adequately warn and instruct Plaintiff and her healthcare providers that that Defendant lacked a safe, effective procedure for removal of the Pelvic Mesh Products, including the Altis Pelvic Mesh Product at issue in this case;

97. The above acts of Defendant constitute violations of the duty of ordinary care and skill owed by the Defendant to Plaintiff.

98. Plaintiff and/or her implanting physician used and was implanted with Defendant's Altis in a manner that was reasonably foreseeable.

99. As the direct and proximate result of Defendant's negligent breach of its aforementioned duties with respect to the Altis, Plaintiff suffered the injuries and damages alleged herein. Specifically, Plaintiff has suffered and in all reasonable probability will continue to suffer from dyspareunia, pelvic pain, groin pain, vaginal pain, pudendal neuralgia, and recurring urinary tract infections, depression, and anxiety, as well as other symptoms and damages, including severe and permanent pain, suffering, disability, impairment of mobility, impairment of sexual function, impairment of bowel and bladder function, subsequent surgical removal of the mesh, loss of enjoyment of life, and economic damages. Plaintiff did not suffer from said injuries prior to implantation of the Altis device,

and upon information and belief would not have suffered these injuries absent implantation of the Altis device. In addition and in the alternative, Plaintiff suffered from pre-existing injuries/conditions which were aggravated, exacerbated, and/or accelerated by implantation of the Altis device.

COUNT IV: BREACH OF EXPRESS WARRANTIES

100. Plaintiff incorporates each and every paragraph of this Complaint by reference as if fully stated herein and further states and, additionally or in the alternative, if same be necessary, alleges as follows.

101. Defendant expressly warranted that its Altis device was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous side effects, and was adequately tested and fit for its intended use.

102. At the time of Defendant's aforesaid express warranties, Defendant knew or should have known, that its Altis device did not conform to these express warranties because its Altis device was not safe and had numerous serious side effects, about which Defendant did not adequately warn.

103. As a direct, foreseeable, and proximate result of Defendant's breach of its express warranties, Plaintiff suffered and will continue to suffer severe and permanent personal injuries, harm, and economic loss.

104. Plaintiff relied on Defendant's express warranties with respect to its pelvic mesh products, including the Altis device.

105. Members of the medical community, including Plaintiff's physicians and other healthcare providers, relied upon Defendant's representations and warranties in

connection with the use, recommendation, description, and implantation of the Altis device.

106. Defendant breached the express warranties because its Altis device was, and is, defective and unreasonably unsafe for its intended use.

107. Defendant expressly represented to Plaintiff, her physicians and her other healthcare providers that its Altis device: (i) was safe and fit for the purposes intended, (ii) was of merchantable quality, (iii) did not produce any dangerous side effects in excess of those risks associated with other treatments for pelvic organ prolapse and stress urinary incontinence, (iv) the side effects it produced were accurately reflected in the warnings, and (v) it was adequately tested and fit for its intended use.

108. Defendant knew, or should have known, that its aforesaid representations and warranties were false, misleading, and untrue because it's the Altis device was not safe and fit for its intended use and caused its users serious injuries of which Defendant did not adequately warn.

109. As a direct, foreseeable and proximate result of Defendant's foregoing acts and omissions, Plaintiff was caused to suffer and did suffer serious and grievous personal injuries, including dyspareunia, pelvic pain, vaginal pain, pudendal neuralgia, and recurring urinary tract infections, permanent and substantial physical deformity, and the loss of the ability to perform sexually, as well as other grievous personal injuries, including, but not limited to, physical pain and mental anguish, permanently diminished enjoyment of life, and any and all additional life implications and complications, such as Plaintiff's need for life-long medical treatment and medical monitoring, and perpetual fear of

developing additional adverse health consequences.

110. As a direct, foreseeable and proximate result of Defendant's foregoing conduct, Plaintiff has suffered and will continue to suffer serious and permanent physical and emotional injuries, has incurred medical expenses, has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured. In addition and in the alternative, Plaintiff suffered from pre-existing injuries/conditions which were aggravated, exacerbated, and/or accelerated by implantation of the Altis device.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief against Defendant as follows:

(1) Compensatory damages according to proof and in an amount to fully compensate Plaintiff for all of her injuries and damages, both past and present;

(2) Special damages according to proof and in an amount to fully compensate Plaintiff for all of her injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income, permanent disability, including, permanent instability and loss of balance, permanent disfigurement, and pain and suffering;

(3) All other damages as allowed by law; and

(4) Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff hereby demands a jury trial on all claims so triable in this action.

Dated: August 29, 2022

Respectfully submitted,

GOLDENBERG LAW, PLLC

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